510(k) Summary for the Rhytec, Inc. Portrait® PSR³

K071786

JUL 26 2007

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter: Rhytec, Inc.
130 Turner Street
Building Two
Waltham, MA 02453

Contact Person: Robert Zoletti
Director, Regulatory Affairs and Quality
Rhytec, Inc.
Telephone: 781-419-9482
Fax: 781-419-9401

Summary Preparation Date: June 22, 2007

2. Names

Device Name: Portrait® PSR³

Classification Name: Electrosurgical cutting and coagulation device
Product Code: GEI

3. Predicate Devices

K060948 - Portrait® PSR³ Rhytec, Inc. Portrait® PSR³

4. Device Description

The Portrait® PSR³ is an electro-surgical device for use in dermatological applications. UHF energy from the generator converts Nitrogen gas into plasma within the handpiece. The plasma emerges from the nozzle at the distal end of the handpiece and is directed onto the skin to be treated. Rapid heating of the skin occurs as the excited gas gives up energy to the skin. Through the combination within the handpiece of precisely controlled energy and Nitrogen gas, individual plasma pulses are produced that will give predictable tissue effects.

5. Indications for Use

The Portrait® PSR³ is indicated for treatment of the following dermatological conditions:

- Treatment of wrinkles and rhytides
- Superficial skin lesions
- Actinic Keratosis
- Viral Papillomata
- Seborrhoeic Keratosis

6. Technological Characteristics

Modifications include:

- Revised the allowable plasma pulse repetition rate from 1 to 4.0 Hz to 1 to 2.5 Hz as recommended in the treatment parameters in K060948.
- Removal of the 12 hour nozzle use life. Nozzle life will continue to be monitored by the number of pulses used.
- Decreased the number of continuous pulses with the foot switch pressed from 120 to 50.
- Added the number of pulses per patient treatment to the display.

7. Clinical and Non-Clinical Data

The device modifications did not raise new questions of safety or efficacy, no performance data is required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Rhytec Incorporated
% Mr. Robert Zoletti
Director, Regulatory Affairs
130 Turner Street, Building Two
Waltham, Massachusetts 02453

JUL 26 2007

Re: K071786
Trade/Device Name: Rhytec, Inc. Portrait®
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 27, 2007
Received: July 2, 2007

Dear Mr. Zoletti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071786

Device Name: Rhytec, Inc. Portrait®
PSR^3

The Portrait® PSR^3 is indicated for treatment of the following dermatological conditions:

- Treatment of wrinkles and rhytides
- Superficial skin lesions
- Actinic Keratosis
- Viral Papillomata
- Seborrhoeic Keratosis

Indications for Use are unchanged from K060948

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Milkerson

(Division Sign-Off)
Division of General Restorative,
and Neurological Devices

510(k) Number K071786